IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO WAVE 8 CASES ON ATTACHED EXHIBIT A	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF DAUBERT MOTION TO PRECLUDE OR LIMIT OPINIONS OF DEFENSE EXPERT C. BRYCE BOWLING

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Plaintiffs respectfully request that this Court exclude certain expert testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson's expert C. Bryce Bowling, M.D. ("Dr. Bowling"). In support of their motion, Plaintiffs state as follows:

INTRODUCTION

This case resides in one of seven MDLs assigned to this Court by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In an effort to manage the massive Ethicon MDL efficiently and effectively, the court decided to conduct pretrial discovery and motion practice on an individualized basis. To this end, Judge Goodwin selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded. This matter is part of Wave 8. Ethicon offers Dr. C. Bryce Bowling, board-certified in Urogynecology, to testify on a number of general causation issues.[1, 2]

Dr. Bowling's experience in the field of Urogynecology does not render all of his opinions admissible.[3] The admission of Dr. Bowling's unfounded opinions is both contrary to law and presents a serious risk of confusing the issues and misleading the jury.[4] As this Court previously noted,"[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles

[1] Wave 8 General Expert Report of C. Bryce Bowling, M.D. for Prolift, Prolift +M and Gynemesh,.at 1 (attached as Ex. B).
[2] Wave 8 General Expert Report of C. Bryce Bowling, M.D. for TVT, TVT-O and TVT Exact at 1 (attached as Ex. C).
[3] Curriculum Vitae of Dr. Bowling is attached as Exhibit D.
[4] *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.') (citing *Daubert*, 509 U.S. at 596).

and methods to the facts of this case.'"[5] Accordingly, Dr. Bowling should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

LEGAL STANDARD

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony ... is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). The Court "need not determine that the proffered expert testimony is irrefutable or certainly correct" – "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.' " *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that

[5] *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, *42-43 (S.D.W.V. 2013).

the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable ... and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.' " (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes....Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

*3 *Daubert*, 509 U.S. at 591-92 (citations and internal quotation marks omitted). The court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

ARGUMENT

I. Dr. Bowling's General Opinions Drawing Legal Conclusions or Performing the Role of a Fact Finder Regarding the Adequacy of the Product Warnings Should Be Excluded.

Dr. Bowling repeatedly drew legal conclusions throughout both reports. For instance, with regard to Prolift/+M, Dr. Bowling opined in his report that the "IFU adequately warned of potential complications."[6] He also opined that "[t]he TVT, TVT-O and TVT Exact Instructions for Use (IFU) are not misleading and adequately warned of the potential complications that could follow."[7] With regard to TVT, TVT-O and TVT-Exact, Dr. Bowling also opined that "[t]he products are not defective and work as intended to address complaints of stress urinary leakage."[8] Dr. Bowling also opined that, "I have never once seen the alleged design defects that plaintiff's experts love to quote" and the 'design defects' are not related to the implant itself."[9] Whether or not the Instructions for Use are "adequate" is not a question for Dr. Bowling. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or

[6] *See* Exhibit B. at 40.
[7] *See e.g.* Exhibit C at 50.
[8] *See* Exhibit C. at 5; *see also* "Plaintiff's Counsel have suggested a number of unproven claims of defective design on the part of TVT, TVT-Exact and TVT-O, including cytotoxicity, adverse and prolonged host-tissue response, chronic inflammation, mesh degradation and others. Cytotoxicity/Adverse Host Tissue Response / Foreign Body Reaction – Claims of a prolonged and adverse tissue response are baseless, as they are extrapolated from animal models or based on studies from different areas of the human body and do not correlate with mesh sling implanted underneath the urethra. As stated above, polypropylene, the entity comprising the TVT family of slings, despite assurances from plaintiff's counsel, has been shown safe and effective for decades." (Emphasis added.) *Id.* at 29.
[9] Exhibit B at 38.

draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).[10] Therefore, the above legal conclusions Dr. Bowling draws in connection with his opinions regarding the "adequacy" of Ethicon's warnings should be excluded.

II. Dr. Bowling's General Opinions Relying on Case Specific Reports, Statements by Plaintiff's Counsel, TV commercials and Sources He Cannot Cttribute Should be Precluded.

Dr. Bowling's General Opinions should be excluded to the extent that he relied on individual case specific reports to form his opinions. Dr. Bowling testified several times that he did, in fact, rely upon case specific opinions in forming his General opinions. For instance, Dr. Bowling testified as follows:

> Q: Doctor, if you would look at Exhibit 7, Page 5, Section 2, and I've highlighted there for your ease of reference, Doctor there is a sentence that says plaintiff's expert, I have reviewed the expert statements of multiple plaintiff's experts for both case specific and general reports.
>
> Do you see that, Doctor?
>
> A: Yes.
>
> Q: Doctor, what case specific reports did you rely on in forming your opinions?
>
> A: Case specific reports. They will be in the reliance list. I looked over expert opinions in the both general reports and case specific reports for several of the cases that I was working on to see what the plaintiff's claims were regarding midurethеral slings.[11]

[10] *Id*.
[11] See Exhibit E (Bowling deposition) at 45:10-46:1.

Dr. Bowling's opinions that "Polypropylene, the material make-up of the [products], despite assurances from Plaintiff's Counsel, has been shown safe and effective for decades" should also be excluded.[12] With regard to these opinions, Dr. Bowling testified that his source was a "combination of seeing commercials on TV".

> Q: And, Doctor, again, I'm just trying to get to sort of the source of what you're referencing there so - -
>
> A: Well, I think my source is a combination of seeing commercials on TV. My source is being deposed several times in the past by plaintiffs' counsel who as you have done today tend to word questions in such a way that makes the mesh seem to be a dangerous product, when I as a surgeon, researcher and scholar know that's not the case.[13]
>
> ***

Dr. Bowling's opinions regarding the alleged testimony or actions of "Plaintiff's Counsel" should be excluded. For instance, Dr. Bowling opined that "[a]ny suggestions by Plaintiff's counsel regarding "mesh degradation" are also not supported by reasonable medical literature."[14] Dr. Bowling, also opined as follows:

> "Plaintiff experts contend that native tissue repairs (or other surgical procedures) would be a safer alternative design to Prolift / Prolift +M. These claims are baseless. There is no clinical evidence supporting plaintiff's counsel claims that a lighter weight, larger pore, partially absorbable mesh would be a safer alternative design."[15]

Yet, Dr. Bowling has no basis for his opinions related to "Plaintiff's Counsel" and refused to name his source. For instance, Dr. Bowling testified:

> Q: And plaintiff's counsel, your references to those, would you like to list the counsel that you attribute to as the source?

[12] Exhibit C at 16 and 28; see also Exhibit "B" at 14.
[13] Exhibit E at 202:10-19.
[14] See e.g. Exhibit B at 39.
[15] See Exhibit B at 39.

A: As I said earlier, I have been deposed several times by plaintiff's counsel pleural, that have made claims in their statements and in their questioning of mesh products. I did not name them. I have not named you. I'm not talking about you, but there have been instances where I have had discussions with plaintiff's counsel where they have made these assurances.

There have also been instances, since we're getting into my discussions with plaintiffs' counsels, there have also been instances where we have gone off the record and plaintiffs' counsel had admitted to me that if their wife needed a mesh midurethral sling, they would have no problem with them having a mesh midureteral sling, that they understood mesh that wasn't a problem.

So if you want to get into conversation about what I've spoken to plaintiffs' counsel, I will be happy to do that, but I'm not going to name people by name.

Q: And that is the basis of your opinions that you're setting out today?

A: Correct. That's---that is a partial basis of my opinions.

Therefore, Dr. Bowling's opinions discussed above should be excluded.

III. Dr. Bowling's Opinions Based on Information Selectively Provided by Counsel, Conflicting Opinions with FDA and Other Studies and Opinions Should be Excluded.

Dr. Bowling's testimony also revealed that his opinions were based on his anecdotal personal experience and that much of the data he reviewed was selectively provided to him by Defendant's counsel. In fact, his reference list is identical in font type and grammatical mistakes as other defense experts.[16] Dr. Bowling freely admits that Defendant's counsel provided him with the materials and the record reflects Dr. Bowling did not put together the reliance list.[17] Dr. Bowling's testimony also shows that he failed to take into consideration conflicting studies, and could not account for those studies.

[16] Exhibit E at 72:1-75:6.
[17] Exhibit E at 73:22-74:8; 75:10-12.

a. Information Selectively Provided by Counsel

Courts have routinely held that an expert's opinions lack reliability where the only materials reviewed were provided by counsel. See *Danley v. Bayer (In re Mirena IUD Prods. Liab. Litig.*), 2016 U.S. Dist. LEXIS 29752, *91-92 (S.D.N.Y. Mar. 8, 2016) (only materials reviewed by expert were "a number of articles supplied to him by Plaintiffs' counsel, which [expert] subsequently copied and pasted into his expert report. . . . This is not the level of rigor an expert in the field would apply and does not pass muster under *Daubert*."), citing *Mancuso v. Consol. Edison Co. of N.*Y., 967 F. Supp. 1437, 1443 (S.D.N.Y. 1997) (finding expert unqualified because he relied on counsel to supply him with relevant scientific literature and "subsequently attempted, with dubious success, to qualify himself as [an expert] by a selective review of the relevant literature"); *Prohaska v. Safamor, S.N.C.*, 138 F. Supp. 2d 422, 437 (W.D.N.Y. 2001) (criticizing "litigation-driven expertise" where expert "relied upon the plaintiff's attorney to provide him with the relevant scientific literature").

This Court confronted a similar – and instructive – issue in *Tyree v. Boston Sci. Corp.*, 2014 U.S. Dist. LEXIS 148312 (S.D. W. Va. Oct. 17, 2014), excluding an expert's testimony where counsel had selectively provided the expert with pathology samples for the expert to review. "The plaintiffs do not explain how or why they chose these twenty-four reports for [the expert's] review, and without such an explanation, I have no way of assessing the potential rate of error or the presence of bias." Id. at *45. The Court noted that it had reached the same conclusion in other cases. Id. See also *Hall v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 23980, *31 (S.D. W. Va. Feb. 27, 2015).

In light of the one-sided, slanted "litigation style" preparation for his testimony, Dr. Bowling is more akin to an advocate than an expert. His testimony should be excluded.

b. Failure to Account for Conflicting Studies and FDA Advisories

Dr. Bowling in his report failed to acknowledge any studies and FDA reports which conflict with his own opinions. Dr. Bowling did not consider a number of peer review articles that found mesh complications. Instead, Dr. Bowling simply countered that he relied on his own experience.[18]

In fact, when questioned further about mesh complications Dr. Bowling testified, "[b]ut do I look at the mesh and say this evil mesh caused this [complication]? No I don't."[19] Furthermore, Dr. Bowling in his report did not account for the FDA's advisory indicating that it is not clear that transvaginal pelvic organ prolapse ("POP") repair with mesh is more effective than traditional non-mesh repair in all patients with POP, instead he disagreed with the FDA statement. (Ex. E at 136:19-22). In fact, many of Dr. Bowling's conclusions ***conflict*** with the FDA's advisories. For instance:

> Q. [Directing witness to read FDA Advisory noting Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA since the October 20th, 2008 FDA Public Health Notification.]
>
> A: You know, I don't think mesh contraction was a previously unidentified risk. . . So no, I don't agree that it was a previously unidentified risk. I think that mesh contraction has been known for some time. I think that clinically relevant mesh contraction is not something that exists.[20]

This Court has repeatedly affirmed throughout this litigation that an expert "may not solely rely on his personal observations, especially when he seeks to provide broad opinions, such as the infection rate in women with mesh." *Frankum v. Boston Sci. Corp*., 2015 U.S. Dist. LEXIS 57251, *24 (S.D. W. Va. May 1, 2015), citing *Daubert v. Merrell Dow Pharms*., 509

[18] Ex. E at 182:12-14.
[19] *Id*. at 182:22-183:8.
[20] *Id*. at 140:2-20.

U.S. 579, 592 (1993). Rather, "[p]roposed testimony must be supported by appropriate validation—i.e., 'good grounds,' based on what is known". Id., citing *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998) (internal citations omitted).

Based on these standards, the Court has repeatedly held that expert testimony is inadmissible where it is based solely on personal experience, unsupported by reliable medical or scientific data. See, e.g., *Sanchez, supra* at *42 (opinions based on personal experience alone, without scientific evidence or studies to support them, are inadmissible); *In re Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 15351, *2602 (S.D. W. Va. Jan. 15, 2014) (expert's "opinion is unreliable because it is merely *ipse dixit*, unsupported by any particular regulations or authorities."); *Tyree, supra* at 524 (testimony unreliable where expert could not cite to a supporting study), citing *Sanchez, supra*, at *17.

Nor may an expert obliquely reference unspecified "publications" which he claims support his views, as Dr. Bowling does in his deposition testimony.[21] *Wise v. C. R. Bard, Inc.*, 2015 U.S. Dist. LEXIS 14869, *25-26 (S.D. W. Va. Feb. 7, 2015) ("without a fully synthesized representation of [expert's] database, specific reliance on that database is unreliable").

Equally telling on the issue of reliability is Dr. Bowling's failure to subject his anecdotal conclusions to peer review.[22] Courts have excluded expert testimony where "instead of using many examples to arrive at a singular conclusion, [the expert] is attempting to rely solely on his own personal experience". *Trevino v. City of Rock Island Police Dep't*, 91 F. Supp. 2d 1204, 1206-1207 (C.D. Ill. 2000). See also *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) (excluding evidence based "entirely on the experts' unadorned assertions that the methodology they employed comports with standard scientific procedures" since "the expert's

[21] *See e.g.* Exhibit B at 24. (Dr. Bowling opined "[o]ther studies have not only confirmed the high failure rates of native tissue repairs but have also pointed out significant suture exposure complications")
[22] *See e.g.* Exhibit D at 181:19-21; 185:5-7.

bald assurance of validity is not enough" to show that the method is based on "scientifically valid principles"); *Bennett v. PRC Public Sector, Inc*., 931 F. Supp. 484, 494, n. 21, and 502, n. 42 (S.D. Tex. 1996) (expert's opinion that defective design of workstation caused plaintiffs' injuries held inadmissible; among other deficiencies, expert's statement that he had "discussed [his conclusion] with my peers and I have gotten concurrence with my thoughts" did not constitute adequate "peer review" under *Daubert*). Even if Dr. Bowling were permitted to testify concerning his personal experiences with the products he observed and opined on in Wave 8, his testimony provides no basis for allowing him to draw broader conclusions. *Wise v. C. R. Bard, Inc*., 2015 U.S. Dist. LEXIS 14869, *46-48 (S.D. W. Va. Feb. 7, 2015) (expert "may testify about the complications he has observed in patients implanted with the Avaulta (without referring to complication rates), but, as I explained in *Eghnayem, et al. v. Boston Scientific Corp*., he lacks the qualifications to infer conclusions from these observations as to the etiology of complications associated with a pelvic mesh device"), citing *Eghnayem, et al. v. Boston Scientific Corp*., No. 2:13-cv-07965, 2014 U.S. Dist. LEXIS 148312, 2014 WL 5320566, at *35 (S.D. W. Va. Oct. 27, 2014).

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court exclude the above opinion testimony from Dr. C. Bryce Bowling. Plaintiffs further request all other relief to which they are entitled.

Respectfully submitted,

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Dated: October 18, 2018.

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on October 18, 2018, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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